The Commissioner of the Food and Drug Administration could find no relationship of the rejections to the quality of the drugs. He stated that: "Many of the statements are unsupported totally by any evidence, either in the paper or by any evidence that he [Mr. Feinberg] has provided to us."

Dr. Crout, the Director of FDA's Bureau of Drugs, said that: "* * * it is clear that most of the violations of GMP's, Good Manufacturing Practices, as we see them are relatively trivial and unrelated to the quality of the drug."

The DOD supplied 12 examples of what Mr. Feinberg characterized as "gross violations." Of the 12 entries, one firm is listed twice, thereby reducing the number of plants to a total of 11. It should be noted that 5 of the 11 examples are plants operated by members of the Pharmaceutical Manufacturers Association.

2. The Department of Defense revealed that only 5 percent of the drug products obtained based upon contracts awarded are, in fact, subjected to laboratory testing. The remaining 95 percent are judged satisfactory based upon other DOD information. In other words, the rejection rate is less than 2.5 percent of the drugs to be bought, not 42 percent.

What are these rejected drugs, and on what basis are they rejected?

According to the FDA Commissioner: "* * * the number of analyses of drugs done there are very small, and the principal analyses are done, not on production run of drugs, but on special runs of drugs done by a new company wishing to make the drug, in many instances, a company that has never made it before. And his 42 percent rejection rate is of a relative handful of drugs on a nonproduction run by companies, some of which have never made it before and have never sold drugs to the DOD before." [See page 9965.]

Now, Mr. Feinberg has never added these important details to his public statements. Instead, he has given the impression that the DOD has refused to accept a very large percentage of drugs which are being used by the American public. Even the President of the Pharmaceutical Manufacturers Association and his counsel, Mr. Cutler, were taken in by Mr. Feinberg.

3. With respect to problems of bioavailability, Mr. Feinberg has tried to give the impression that this is a serious problem with many drugs on the market. The DPSC stated that its employees knew about the digoxin problem in 1965. Dr. Crout, the Director of the FDA's Bureau of Drugs, said that the methodology which enabled the discovery of the problem was not available until 1969. Furthermore, digoxin is a very important drug and critical to many patients, and if, as DPSC claimed, they "knew" that this drug had problems, why didn't they inform the FDA about it?

As for the other drugs Mr. Feinberg says have bioavailability problems, Dr. Schmidt testified that Mr. Feinberg has provided the FDA with "no specific, special evidence of bioavailability problems that he has that we do not have. The drugs that he mentions as having bioavailability problems generally everybody knows and